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EXAMINER

WALLENHORST, MAUREEN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1743

DATE MAILED: 07/18/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/600,094

Applicant(s)

BUCHWALD ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Claims 2-13, 15-23, 25-27 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 4 of claim 2, the phrase "a blood level of oxygen" is indefinite since it is not clear what this refers to. Does this refer to the oxygen located outside of the membrane of the red blood cell in the blood sample of the patient? See this same problem in claims 25, 27 and 29.

In claim 15, the phrase "being adapted and configured to/for" is indefinite since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. See In re Hutchison, 69 USPQ 138. Therefore, the functions of the red blood cell transport system, the gas exchange system and the oxygen level detector recited after the phrase "being adapted and configured to/for" have not been given any patentable weight. See this same problem on lines 4-5 of claim 19, on lines 4-5 of claim 22 with the phrase "being arranged and configured for", and on lines 3-4 of claim 23 with the phrase "being arranged and configured for".

Claim 22 is indefinite since the cartridge-type insert has not been positively recited as a component of the apparatus. Therefore, the structural relationship between the insert and the other components of the apparatus is not clear. See this same problem in claim 23 with the "modular system".

On line 3 of claim 26, the phrase --from a patient-- should be inserted after the word "sample" since the method is performed on a blood sample from a patient. On the last line of claim 24, the phrase --measured at an earlier time-- should be inserted after the phrase "previous

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lipid level" so as to make it clear that the patient's lipid level is measured at different points in time.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-14 and 24-27 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of prior U.S. Patent No. 6,037,181. This is a double patenting rejection.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 28-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 6-8 of U.S. Patent No. 6,037,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 and 6-8 of US Patent no. 6,037,181 encompass a method for determining a patient's blood oxygen transport since these claims recite the same steps as claims 28-33 of the instant application, i.e. both sets of claims recite the steps of obtaining a blood sample from a patient and measuring the rate of oxygen diffusion across a membrane of a red blood cell in the blood sample.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 15, 17, 19-20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Page et al. (from Chapter 9- Exp. Simulation of Oxygen Transport in Microvessels cited in the Information Disclosure Statement filed December 29, 2000).

Page et al. teach of an apparatus for measuring diffusion of oxygen across a red blood cell membrane, which comprises a microflow system that serves as a red blood cell transport system, an oxygen level detector and a gas exchange system. The gas exchange system comprises a capillary imbedded in a thin film of silicone rubber. Test blood samples are held in a reservoir and withdrawn by a syringe pump that acts as the red blood cell transport system into the capillary lumen where gas exchange occurs. In an oxygen uptake experiment, both surfaces

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of the capillary are exposed to humidified air and a fully deoxygenated sample is oxygenated as it flows through the lumen of the capillary. In an oxygen release experiment, both surfaces of the capillary are exposed to humidified nitrogen and a fully saturated blood sample is deoxygenated as it flows through the lumen of the capillary. A shroud surrounds the capillary and serves as a housing that holds the desired oxygen atmosphere around the capillary. The shroud has windows at the top and bottom to allow the passage of light. The oxygen level detector comprises a microspectrophotometer which makes absorbance measurements at various axial positions along the capillary.

It appears that this reference to Page et al. was published in 1996 since the other Page et al. article cited in the Information Disclosure Statement dated 12-29-00 (from Microvascular Research) indicates that this Page et al. reference, in the lower right hand corner of page 55, was published in 1996.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 16, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. in view of Applicants' admitted prior art. For a teaching of Page et al. (from Chapter 9- Exp. Simulation of Oxygen Transport in Microvessels cited in the Information Disclosure

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Statement filed December 29, 2000), see previous paragraphs in this Office action. Page et al. fail to teach that the oxygen level detector can be an oxygen electrode or a fluorometric detector.

Applicants admit on lines 1-10 of page 5 in the instant specification that oxygen levels in blood are known in the art to be measured by spectrophotometric methods, fluorometric methods and potentiometric methods utilizing oxygen electrodes. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use an oxygen electrode or a fluorometric detector in place of the spectrophotometric detector taught by Page et al. as the oxygen level detector since these are both known prior art methods of measuring oxygen levels in blood equivalent in function to a spectrophotometric detector.

It also would have been obvious to one of ordinary skill in the art to use a peristaltic pump in place of the syringe pump taught by Page et al. for transporting a red blood cell sample to the capillary gas exchange system in the apparatus of Page et al. since a peristaltic pump is known in the art to perform the equivalent functions of a syringe pump for injecting and transporting fluid samples.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is (703) 308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7719.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

mmw

July 11, 2002

*Maureen M. Wallenhorst*  
MAUREEN M. WALLENHORST  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1700